

REMARKS

Claims 11-32 are pending in the present application.

The rejection of Claims 11, 14-15, and 17-18 under 35 U.S.C. §102(b) over Rovee et al. (U.S. 4,185,100) is obviated by amendment.

Rovee et al. relates to a pharmaceutical composition for topical treatment of skin disorders. Substantially, the disclosure of Rovee et al. relates to compositions that are a liquid preparation for topical administration and contain one or more solvents, including ethanol and propylene glycol (see, for example, column 3, lines 25-26, Table A, and Table B). However, preparations for topical administration do not contain propellants.

In regard to the propellants, the Examiner points to the Table under sub-heading "F. Aerosol" appearing in column 7. In sub-heading "F. Aerosol" Rovee et al. disclose that aerosol formulations can be obtained in accordance with their invention. To this end, Rovee et al. state that a propellant may be used. However, the only propellant disclosed therein is the propellant appearing in the Table that provides the composition for a quick breaking alcoholic foam. The propellant disclosed by Rovee et al. is a mixture of CFC 12/114 propellants (see column 7, line 22).

The present invention as defined by Claim 11 has been limited to HFA propellants. At no point do Rovee et al. disclose or suggest an HFA propellant. The standard for determining anticipation requires that the reference "must teach every element of the claim" (MPEP §2131). In view of the absence of a disclosure or suggestion of a HFA propellant by Rovee et al., this reference clearly cannot anticipate the claimed invention.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejection of Claims 11 and 15-23 under 35 U.S.C. §103(a) over Keller et al. (WO98/34595) is obviated in part by amendment and traversed in part.

Keller et al. disclose a pressure-liquified propellant mixture for aerosols, where the mixture contains as required ingredients a fluorinated alkane (e.g., 1,1,1,2-tetrafluoroethane and/or 1,1,1,2,3,3,3-heptafluoropropane) and carbon dioxide (see, for example, Abstract, page 5, lines 23-25, and the claims). In contrast to the disclosure of Keller et al., in the present invention the propellant is defined as being one or more hydrofluoroalkanes. Therefore, the propellant defined in Keller et al. is distinct from that of the present invention.

Furthermore, Applicants note that Keller et al. discloses their pressure-liquified propellant mixture as being useful with virtually every known class of active compounds (see page 15, line 15 to page 17, line 24). It appears the Examiner's position that the mere suggestion in Keller et al. of active compounds that may fall within the scope of the claims is sufficient to establish a *prima facie* case of obviousness. Applicants disagree and further note none of the examples of Keller et al contain an active compound within the scope of the present invention. The only Example that even contains a corticosteroid in an HFA propellant is Example 1; however, the steroid used in this example is Beclometasone dipropionate, which is not within the scope of the claimed invention. Further, Applicants note that Examples 4 and 5, which also disclose a steroid only do so in the presence of an HFA/CO₂ propellant. In these Examples, the remaining limitations of the presently claimed invention are not present (i.e., the cosolvent). As such, Keller et al. fail to disclose the

present invention with sufficient specificity, much less provide the requisite expectation of the advantageous properties flowing from the claimed invention, which are clearly shown in the examples of the present specification (see pages 12-27).

In view of the foregoing, Applicants submit that the present invention is not obvious in view of the disclosure of Keller et al. Therefore, withdrawal of this ground of rejection is requested.

The rejections of: (a) Claims 11, 16-19, 21-23, 26, and 28-30 under 35 U.S.C. §103(a) over Cutie (U.S. 5,891,419), and (b) Claims 12-15, 20, 24, 25, 27, 31, and 32 under 35 U.S.C. §103(a) over Cutie (U.S. 5,891,419) in view of Radhakrishnan et al. (U.S. 5,192,528), are traversed.

Cutie discloses aerosol formulations for oral inhalation containing flunisolide dispersed in HFC 134a and/or HFC 227 (see Abstract). The aerosol formulations disclosed by Cutie are free of CFCs and surfactants, and contain little or no ethanol. In regard to the small amounts of ethanol, Cutie discloses at column 4, lines 5-16 that ethanol is present to *prevent dissolution* of the flunisolide. However, this disclosure is directly at odds with the present invention wherein a cosolvent (e.g. ethanol) is used to *dissolve* the active ingredient in the propellant (see, for example, pages 10-12 and the Examples). From this disclosure by Cutie, it is clear that ethanol is not a cosolvent as used in the present invention as its function in the aerosol formulation is substantially different from that of a cosolvent, which is presently claimed.

Applicants note that MPEP §2141.02 states: "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In view of the disclosure at column 4, lines 5-16, Applicants note that Cutie teaches away from the inclusion of ethanol as a cosolvent. Therefore, the disclosure by Cutie fails to render the present invention obvious.

The Examiner cites Radhakrishnan et al. as disclosing specific antioxidants and budesonide. However, Radhakrishnan et al. fails to compensate for the deficiency note above for Cutie. Moreover, Applicants note that the formulation disclosed by Radhakrishnan et al. is in the form of an aqueous liposome suspension. Such a formulation is physically distinct from the formulation of the present invention, as well as Cutie, which is an aerosol formulation.

Applicants note that the mere fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness (MPEP §2143.01). Applicants remind the Examiner that "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." (*In re Fritch* 23 USPQ2d 1780, 1783 (Fed. Cir. (1992)). In view of the differences noted above in the type of formulation disclosed in Cutie and Radhakrishnan et al., Applicants note that absent a specific suggestion or incentive in the references themselves there would be no motivation to combine the disclosures of Cutie and

Radhakrishnan et al. As such, the present invention is not obvious in view of the disclosures of Cutie and Radhakrishnan et al.

Withdrawal of this ground of rejection is requested.

Applicants respectfully request that the provisional obviousness-type double patenting rejection of Claims 11-32 over the claims 1-13 of U.S. 10/244,519 be held in abeyance until an indication of allowable subject matter in the present application. If necessary, a terminal disclaimer may be filed at that time. Until such a time, Applicants make no statement with respect to the propriety of this ground of rejection.

However, Applicants remind the Examiner that, with respect to a provisional double patenting rejection between co-pending applications, MPEP §804 states:

If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

Accordingly, if the present amendment places the elected claims in condition for allowance, Applicants note that the provisional obviousness-type double patenting rejection over U.S. 10/244,519 should be withdrawn if that application is not in condition for allowance.

Finally, Applicants remind the Examiner that originally presented Claims 11-32 correspond substantially to Claims 1-28 of U.S. application serial No. 10/176,851, to Buenafae et al. published as US 2003/0053957 A1 on March 20, 2003 (Buenafae et al.).

Application Serial No. 10/612,072
Response to Office Action mailed September 23, 2004

Applicants filed a 37 CFR 1.604 request for an interference with Buenafae et al. in a copending divisional application of U.S. application serial No. 10/435,354. The copending divisional application of U.S. application serial No. 10/435,354 was filed on July 3, 2003 and has been assigned the serial number U.S. application serial No. 10/612,067.

The present application was filed in the event that an interference is declared between Buenafae et al. and U.S. application serial No. 10/612,067 and Buenafae et al. move to have compositions containing budesonide as the active agent removed from the count on the ground of patentable distinctness. In that event, Applicants would move to have the present application added to the interference.

However, based on the Office's Patent Application Information Retrieval (PAIR) system, it appears that Buenafae et al. (U.S. application serial No. 10/176,851) was officially abandoned on November 17, 2004, due to non-response to the final Office Action mailed on April 7, 2004. Further, the PAIR system also shows that the parent application to Buenafae et al. (U.S. application serial No. 09/768,915) was also abandoned (officially abandoned on June 27, 2002), as was a second continuation application based on the '915 application (U.S. application serial No. 10/056,962, officially abandoned on June 15, 2004). Since the PAIR system no longer shows any pending applications in the Buenafae et al. family of applications, it is believed that the 37 CFR 1.604 request for an interference filed in U.S. application serial No. 10/612,067 is now moot. If this is indeed correct, Applicants will file a request to withdraw the 37 CFR 1.604 request for an interference in U.S. application serial No. 10/612,067.

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Applicants respectfully submit that the above-identified application is now in condition for allowance, and early notice of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Stephen G. Baxter
Registration No. 32,884

Vincent K. Shier, Ph.D.
Registration No.: 50,552

Customer Number

22850

Tel: 703-413-3000
Fax: 703-413-2220
SGB:VKS